K062126

510(k) Summary
EmboCath® Plus Infusion Microcatheter
BioSphere Medical, Inc.

AUG - 9 2006

1. SUBMITTER/510(K) HOLDER

BioSphere Medical, Inc.
1050 Hingham Street
Rockland, MA 02370 USA

Contact Person: Irina Kulinets
Sr. Director Regulatory Affairs and Quality Assurance
Telephone: 781-681-7900

Fax: 781-681-5093

Date Prepared: July 26, 2006

2. DEVICE NAME

Proprietary Name: EmboCath® Plus Infusion Microcatheter
Common/Usual Name: Infusion Catheter
Classification Name: Catheter Intravascular Diagnostic (21CFR 870.1200, DQO)

3. PREDICATE DEVICES

- EmboCath Hydrophilic Catheter (K003105)

4. DEVICE DESCRIPTION

The EmboCath® Plus Infusion Microcatheter, same as its predicate device EmboCath Hydrophilic Catheter (K003105) is sterile, biocompatible, single use, peripheral vascular catheter constructed of a tapered reinforced shaft, inner lubricious lined lumen, hydrophilic outer surface, radiopaque marker and a standard luer adapter at the proximal end.

The device will be provided in the following configurations:

- Inner Diameter: 0.028 in.
- Outer Diameters: 3 F proximally to 2.8 F distally
- Lengths: 100 cm and 135 cm as indicated on product label

5. INTENDED USE

The EmboCath® Plus Infusion Microcatheter is intended for: infusion of various diagnostic, embolic and therapeutic agents into the body's peripheral vascular systems, guidewire exchange/support; and superselective angiography of the peripheral vasculatures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

BioSphere Medical, Inc. bases its claim of the substantial equivalence of the EmboCath® Plus Infusion Microcatheter with the cited predicate device based on intended use, indications for use, fundamental technological characteristics, and fundamental operational characteristics. The function of the EmboCath® Plus Infusion Microcatheter is to facilitate the access of distal vasculature over a guidewire and deliver various diagnostic, embolic and therapeutic agents into the body's peripheral vascular systems.

The EmboCath® Plus Infusion Microcatheter is a tapered 3.0-2.8F single lumen catheter designed to facilitate the access of distal vasculature over a guidewire. The catheter has a semi-rigid proximal shaft and becomes progressively more flexible toward the distal end. The shaft is reinforced, which provides improved torque transmission. The inner lumen is lined with a lubricious material to facilitate the movement of guidewires or other devices. The outer diameter of the catheter is coated with a hydrophilic surface to enhance the ability to navigate tortuous anatomy. The distal tip of the catheter has a single radiopaque marker to facilitate fluoroscopic visualization. The hub at the proximal end incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter lumen is 0.028 inches and guidewires measuring up to 0.025 inches (0.635 mm) in diameter are recommended.

7. PERFORMANCE TESTING

In-vitro design verification and validation testing demonstrates that the EmboCath® Plus Infusion Microcatheter is equivalent to its predicate device and fulfills design and performance specifications.

The following design verification testing were performed:

- Visual Inspection
- Dimensional Inspection

- Trackability Test (in simulated anatomy)
- Kink Resistance Test
- Patency Test (for embolic patency)
- Coating Lubricity Test
- Aspiration Test
- Stiffness Test
- Tensile Failure Load Test
- Column Test
- Leak/Burst Test (Static Pressure)

8. PRODUCT FEATURE COMPARISON

Feature	EmboCath® Plus Infusion Microcatheter Subject device	EmboCath Hydrophilic Infusion Catheter (K003105) Predicate device
Intended Use	The EmboCath® Plus Infusion Microcatheter is intended for: infusion of various diagnostic, embolic and therapeutic agents into the body's vascular systems (peripheral) guidewire exchange/support; and superselective angiography of the peripheral vasculatures.	The EmboCath® Plus Infusion Microcatheter is intended for: infusion of various diagnostic, embolic and therapeutic agents into the body's vascular systems (neuro, peripheral, coronary) guidewire exchange/support; and superselective angiography of the peripheral and coronary vasculatures.
Design: Length	100 cm and 135 cm	100 cm and 135 cm
Design: Internal Diameter	0.028 in.	0.028 in.
Design Outer Diameter:	0.038 in. distal 30 cm 0.039 in. proximal (65 cm and 70 cm)	0.038 in. distal 30 cm 0.039 in. proximal (65 cm and 70 cm)
Materials	Predominantly Pebax, Nylon12, Stainless Steel, Polyvinylpyrrolidone (PVP), Polyachrylamide	Predominantly Pebax, Nylon12, Stainless Steel Polyvinylpyrrolidone (PVP)

9. SUMMARY OF SUBSTANTIAL EQUIVALENCE

Biosphere Medical, Inc determination of substantial equivalence to EmboCath Hydrophilic Catheter (K003105) predicate device is based on the following.
The subject catheter is substantially equivalent to EmboCath Hydrophilic Catheter (K003105) with respect to:

- Size
- Construction
- Intended use
- Performance characteristics
- Biocompatibility
- Packaging
- Sterilization method

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2006

BioSphere Medical, Inc.
c/o Ms. Irina Kulinets
1050 Hingham Street
Rockland, MA 02370

Re: K062126
EmboCath Plus Infusion System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (Two)
Product Code: DQO
Dated: July 26, 2006
Received: July 26, 2006

Dear Ms. Kulinets:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062126

Device Name: EmboCath® Plus Infusion Microcatheter

Indications For Use:

The EmboCath® Plus Infusion Microcatheter is intended for:

infusion of various diagnostic, embolic and therapeutic agents into the body's peripheral vascular systems, guidewire exchange/support; and superselective angiography of the peripheral vasculatures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation~~ (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062126